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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,093	02/07/2004	Shyam K Gupta		2092

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EXAMINER
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BROOKS, KRISTIE LATRICE

ART UNIT	PAPER NUMBER
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1616

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03/19/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/708,093	<b>Applicant(s)</b> GUPTA, SHYAM K	
	<b>Examiner</b> KRISTIE L. BROOKS	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7 and 14-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application***

1. Claims 1,3-5,7, and 14-21 are pending. Claims 14 to 21 are pending.
  2. Receipt and consideration of Applicants amendments filed on June 2, 2008 is acknowledged.
  3. Rejections not reiterated from the previous Office Action are hereby withdrawn.
- The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Garlen et al. (US 4,707,354).

Garlen et al. teach sunscreen, protectant, moisturizing, dermatological compositions containing oxybenzone, ethyl 4-[bis(hydroxypropyl)]aminobenzoate, padimate O and 2-phenylbenzimidazole-5-sulfonic acid, and skin protectants allantoin and dimethicone, in a cosmetically and therapeutically acceptable carrier and vehicle, containing suitable solvents moisturizers, humectants, oils, emulsifiers, thickeners, thinners, surface active agents, fragrances, preservatives, antioxidants and the like (see

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the entire article, especially column 2 lines 40-51). The compositions may be provided in a form of a cream, emulsion, lotion, spray, ointment, mousse or foam mask (see the entire article, especially column 2 lines 67- column 3 lines 1-2). The following example illustrates compositions of the present invention in the form of a dermatological cream comprising:

<b>Ingredient</b>	<b>Weight Percent</b>
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Oxybenzone	3
ethyl 4-[bis(hydroxypropyl)]aminobenzoate	2
padimate-O 7 2-phenylbenzimidazole-5-sulfonic acid	2
Allantoin	1
Dimethicone	1.25
Deionized water	44
Petroleum	5
Sodium lactate	5
Tyrosine	1
Cysteine	1
Cystine	1

(see the entire article, especially the Example in column 3 lines 9-68 through column 4 lines 1-7 and claim 5).

### ***Response to Arguments***

Applicant's arguments filed June 2, 2008 have been fully considered but they are not persuasive.

Applicant argues that the teachings of Garlen et al. do not apply to the present invention as none of the agents or compositions of Garlen et al. is included in the present invention in its currently amended form.

This argument is not persuasive. The current claims are drawn to a topical skin darkening composition comprising: (i) at least one tyrosinase substrate composition,

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and (ii) at least one tyrosinase activator composition. Garlen et al. teach and exemplifies a tyrosinase substrate (i.e. tyrosine) and a tyrosinase activator (i.e. cysteine). Thus, the limitations of the instantly rejected claims are met. Therefore, the rejection is maintained.

### ***New Grounds of Rejection***

6. Claims 1,4,15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchese et al. (US 5,061,480)

Marchese et al. teach a skin tanning composition comprising nonionic surfactants and an active tanning ingredient, tyrosine (see the abstract and column 4 lines 14-19). Additional active agents such as adenosine triphosphate, riboflavin may be included in the mixture (see column 4 lines 31-39). The mixture of tyrosine, adenosine triphosphate is commercially available under UNIPERTAN 242 (see column 4 line 39). Example 2 discloses a composition comprising

Ingredients	Wt. %
Sterilized water	51.75
Carbomer 940	0.30
ARLACEL 20	5.00
Polysorbate	1.00
Cocoa butter	4.50
Methyl Paraben	0.25
Propyl paraben	0.10
Dimethicone-200 (700 cps)	1.00
UNIPERTAN 242	5.00
GERMAL II	0.50
Tetrasodium EDTA	0.30
Biotin	1.00
Protein hydrolysate	10.00
Triethanolamine	1.22
Fragrance	0.25
<b>TOTAL</b>	<b>100.00</b>

(see Example 2 in column 5).

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***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1,3-5, 7, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (US 5,603,923).

Applicant claims a topical skin darkening composition comprising: (i) at least one tyrosinase substrate composition, and (ii) at least one tyrosinase activator composition.

**Determination of the scope and content of the prior art**

**(MPEP 2141.01)**

Robinson et al. teach artificial tanning compositions that provide improved color development and good chemical physical stability (see the entire article, especially the abstract). The composition comprises (a) from about 0.1% to 20% dihydroxyacetone, (b) from about 0.1 to about 10% of an amino acid such as cysteine, tyrosine, etc., or

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mixture thereof, and (d) a topical carrier (see the entire article, especially column 4 lines 13-25 and claim 1). The topical carrier can be in the form of an emulsion including, oil-in-water, water-in-oil, water-in-oil-in-water emulsions (see the entire article, especially column 9 lines 24-27). These emulsions can cover a broad range such as creamy lotions, and light and heavy creams (see the entire article, especially column 9 lines 28-32). The topical carrier preferably comprises from about 70% to about 99% in all embodiments of the invention (see the entire article, especially column 10 lines 9-11). The compositions of the present invention can also comprise additional components such as humectants, skin protectants, colorants, preservatives, surfactants, and pH adjusters for example (see the entire article, especially column 10 lines 55-67 through column 11 lines 1-5).

### **Ascertainment of the difference between the prior art and the claims**

#### **(MPEP 2141.02)**

Robinson et al. do not teach an exemplified formulation of a topical skin darkening composition comprising: (i) at least one tyrosinase substrate composition, and (ii) at least one tyrosinase activator composition.

### **Finding of prima facie obviousness**

#### **Rational and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a topical skin darkening composition comprising:

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(i) at least one tyrosinase substrate composition for melanin synthesis boost, and (ii) at least one tyrosinase activator composition.

One of ordinary skill in the art would have been motivated to do this because Robinson et al. suggests artificial tanning compositions comprising (a) from about 0.1% to 20% dihydroxyacetone, (b) from about 0.1 to about 10% of an amino acid such as cysteine (i.e. tyrosinase activator), tyrosine (i.e. tyrosine substrate), etc., or mixtures thereof, and (d) a topical carrier. Thus, the instant components are all common additives in skin darkening compositions.

Therefore, the claimed invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

### ***Response to Arguments***

Applicant's arguments filed June 2, 2008 have been fully considered but they are not persuasive.

Applicant argues that the instant invention teaches additional agents (i.e. dihydroxyacetone, carrier) that are not required by the instant claims.

This argument is not persuasive. The current claims are drawn to a topical skin darkening composition comprising: (i) at least one tyrosinase substrate composition, and (ii) at least one tyrosinase activator composition. The instant claims utilize “comprising” language which does not limit any additional materials from being incorporated into the composition. Therefore, the instant limitation is met by a



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composition comprising cysteine (i.e. tyrosinase activator) and tyrosine (i.e. tyrosine substrate). Therefore, the rejection is maintained.

9. Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (US 5,603,923) in view of Bhagyalakshmi et al. (US 2002/0166182).

Applicant claims a topical skin darkening composition comprising: (i) at least one tyrosinase substrate composition, and (ii) at least one tyrosinase activator composition.

#### **Determination of the scope and content of the prior art**

##### **(MPEP 2141.01)**

Robinson et al. teach artificial tanning compositions that provide improved color development and good chemical physical stability (see the entire article, especially the abstract). The composition comprises (a) from about 0.1% to 20% dihydroxyacetone, (b) from about 0.1 to about 10% of an amino acid such as cysteine, tyrosine, etc., or mixture thereof, and (d) a topical carrier (see the entire article, especially column 4 lines 13-25 and claim 1). The topical carrier can be in the form of an emulsion including, oil-in-water, water-in-oil, water-in-oil-in-water emulsions (see the entire article, especially column 9 lines 24-27). These emulsions can cover a broad range such as creamy lotions, and light and heavy creams (see the entire article, especially column 9 lines 28-32). The topical carrier preferably comprises from about 70% to about 99% in all embodiments of the invention (see the entire article, especially column 10 lines 9-11).

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The compositions of the present invention can also comprise additional components such as humectants, skin protectants, colorants, preservatives, surfactants, and pH adjusters for example (see the entire article, especially column 10 lines 55-67 through column 11 lines 1-5).

### **Ascertainment of the difference between the prior art and the claims**

#### **(MPEP 2141.02)**

Robinson et al. do not teach the tyrosinase substrate, Mucuna pruriens extract. This deficiency is cured by the teachings of Bhagyalakshmi et al.

Bhagyalakshmi et al. teach a coloring system for the hair and skin comprising a material and or extract obtainable from the Mucuna plant (see the abstract). It is found that it is possible to obtain superior darker color on hair and skin using a coloring system which comprises the Mucuna plant or its extract (see page 1 paragraph 14). Any Mucuna species may be used. Examples include Mucuna pruriens (see page 2 paragraph 41).

### **Finding of prima facie obviousness**

#### **Rational and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate a Mucuna pruriens extract into the topical skin darkening composition taught by Robinson et al. because it is a known component that is capable of darkening the skin as suggested by Bhagyalakshmi et al.

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One of ordinary skill in the art would have been motivated to do this because Robinson et al. suggests the Mucuna plant or its extract is useful in obtaining superior darker color on the skin. Thus, it is prima facie obvious to combine two skin darkening compositions, taught to be useful for the same purpose. *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980). Therefore, the skin darkening effect of the compositions taught by Robinson et al., will be enhanced by the addition of the Mucuna pruriens extract.

Therefore, the claimed invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

### ***Conclusion***

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristie L. Brooks whose telephone number is (571) 272-9072. The examiner can normally be reached on M-F 8:30am-6:00pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KB

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616